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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 February 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	[...] (2022) XXX draft - D079391
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of certain UV filters in cosmetic products

Delegations will find attached document [\[...\]](#)(2022) XXX draft - D079391.

Encl.: [\[...\]](#)(2022) XXX draft - D079391



Brussels, **XXX**
[...](2022) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council
as regards the use of certain UV filters in cosmetic products**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../... of **XXX amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of certain UV filters in cosmetic products**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products¹, and in particular Article 31(1) thereof,

Whereas:

- (1) The substances 2-Hydroxy-4-methoxybenzophenone/Oxybenzone (CAS no 131-57-7), which has been assigned the name Benzophenone-3 under the International Nomenclature of Cosmetic Ingredients (INCI), and 2-Cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester/Octocrylene (CAS no 6197-30-4), which has been assigned the name Octocrylene under the INCI, are currently allowed as UV filters in cosmetic products and listed in entries 4 and 10, respectively, of Annex VI to Regulation (EC) No 1223/2009.
- (2) In light of concerns related to potential endocrine disrupting properties of Benzophenone-3 and Octocrylene, when used as UV filters in cosmetic products, a call for data was launched in 2019. Stakeholders submitted scientific evidence to demonstrate the safety of Benzophenone-3 and Octocrylene as UV filters in cosmetic products. The Commission requested the Scientific Committee for Consumer Safety (SCCS) to carry out a safety assessment of both substances in view of the information provided.
- (3) Based on the safety assessment and considering the concerns related to potential endocrine disrupting properties of Benzophenone-3, the SCCS concluded in its opinion of 30-31 March 2021² that Benzophenone-3 is not safe for the consumer when used as a UV filter up to the current maximum concentration of 6 % in sunscreen products, either in the form of body cream, sunscreen propellant spray or pump spray.
- (4) The SCCS further concluded that Benzophenone-3 is safe for the consumer when used as a UV filter up to a maximum concentration of 6 % in face cream, hand cream, and lipsticks, and that the use of Benzophenone-3 up to 0,5 % in cosmetic products to protect the cosmetic formulation is safe for the consumer.
- (5) The SCCS also found that the use of Benzophenone-3 as a UV filter is safe for the consumer up to a maximum concentration of 2,2 % in body creams, in propellant

¹ OJ L 342, 22.12.2009, p. 59.

² SCCS (Scientific Committee on Consumer Safety), Opinion on Benzophenone-3 (CAS No [131](#)-57-7, EC No 205-031-5), preliminary version of 15 December 2020, final version of 30-31 March 2021, SCCS/1625/20
https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_247.pdf

sprays and in pump sprays, if there is no additional use of Benzophenone-3 at 0,5 % in the same formulation for protecting the cosmetic formulation. It further concluded that, where Benzophenone-3 is also used at 0,5 % in the same formulation, the levels of Benzophenone-3 used as a UV filter should not exceed 1,7 % in body creams, in propellant sprays and in pump sprays.

- (6) With regard to the substance Octocrylene, the SCCS concluded, based on the safety assessment and considering the concerns related to its potential endocrine disrupting properties, in its opinion of 30-31 March 2021³ that Octocrylene is safe as a UV-filter at concentrations up to 10 % in cosmetic products when used individually.
- (7) The SCCS also found that the use of Octocrylene is safe for a combined use of sunscreen cream or lotion, sunscreen pump spray, face cream, hand cream and lipstick at a concentration up to 10 %, but that the use of Octocrylene at concentrations of 10 % or above in sunscreen propellant spray is not safe for the combined use. The SCCS considered the use of Octocrylene in such products safe when its concentration does not exceed 9 %, when used together with face cream, hand cream, or lipstick containing 10 % Octocrylene.
- (8) In light of the SCCS opinions, it can be concluded that there is potential risk to human health arising from the use of Benzophenone-3 and Octocrylene as UV filters in cosmetic products in the concentrations currently allowed. Therefore, the use of Benzophenone-3 and Octocrylene should be restricted to the maximum concentrations proposed by the SCCS.
- (9) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (10) The industry should be allowed reasonable periods of time to adapt to the new requirements, including by making the necessary adjustments to product formulations in order to ensure that only cosmetic products complying with the new requirements are placed on the market. The industry should also be allowed a reasonable period of time to withdraw cosmetic products which do not comply with those requirements.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex VI to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

³ SCCS (Scientific Committee on Consumer Safety), Opinion on Octocrylene (CAS No 6197-30-4, EC No 228-250-8), preliminary version of 15 January 2021, final version of 30-31 March 2021, SCCS/1627/21 https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_249.pdf

Done at Brussels,

*For the Commission
The President
Ursula von der Leyen*